

CANCER THERAPY EVALUATION PROGRAM, NATIONAL CANCER INSTITUTE

NCI Common Toxicity Criteria (CTC)

VERSION 2.0 – JULY 22, 1999

INTERACTIVE WEB APPLICATION USER'S GUIDE

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Division of Cancer Treatment and Diagnosis (DCTD)

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Before You Begin

Introduction

Capital Technology Information Services, Inc. (CTIS) developed the Common Toxicity Criteria (CTC) Interactive Web Application for the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI). The intent of the CTC Interactive Web Application is to provide a tool to familiarize the user with the grading criteria used for adverse events experienced by patients enrolled on cancer clinical trials using investigational agents. The application can be used to look through the adverse event information included in the *Common Toxicity Criteria Version 2.0* document or to enter patient data and generate reports. There is no database associated with the application from which the user can store and maintain data. The user generates reports at the end of each session as either standard or comma delimited text files for importing to other software. Persons wishing to access the application can do so directly from CTEP's Home Page without a user account or password.

With this application, users can:

- Browse *Common Toxicity Criteria Version 2.0* adverse event criteria,
- Enter information,
- Review entries,
- Create reports, and
- Import comma delimited text into any spreadsheet application.

The adverse event data provided in the application can be located in the Cancer Therapy Evaluation Program, Common Toxicity Criteria, Version 2.0 (CTC, v2.0) document. The document uses the term "toxicity" for historical reasons, but recommends that the term "adverse event" be used instead whenever possible.

CTEP and CTIS welcome your comments and suggestions and will make every effort to incorporate useful suggestions into our procedures, software, and documentation.

What this guide provides

This guide provides comprehensive instructions on how to use the CTC Interactive Web Application. The information (or data element) needed from the user, and how to enter it into the system is described separately for each named CTC screen. The

instruction this guide presents for each of the three possible adverse event search methods follow the same order in which they appear from the CTC Interactive Web Application Main Menu screen.

Conventions used in this guide

Users of the CTC Interactive Web Application should have a working knowledge of the Microsoft Windows operating system. The commands, dialog boxes, names of data elements, and the menus you are asked to activate in this guide appear in **Bold** text. Other references or information the user is asked to enter appear in *Italics*. The term **Click** is used when the mouse pointer is moved to a named item and the left mouse button is pressed once.

Conventions used in the CTC Interactive Web Application

When navigating through the CTC Interactive Web Application, the browser's toolbar (back and forward buttons) should not be used; instead the links (underlined, blue text) are used when displayed in the application. Several CTC screens are divided into different frames. The size of any frame can be adjusted by dragging the frame dividers in the desired direction. Several frames have scroll bars that enable the user to view unseen portions of the screen.

Any listed options or values shown as a link (underlined, blue text), are available for selection. When the mouse pointer is moved over an optional selection, the pointer changes from an arrow to a pointing hand. Any previously selected link will appear in maroon text.

While working with the CTC Interactive Web Application, any link that is accessed changes from underlined, blue text to maroon text. This is referred to as *Navigation History*. The Navigation History assists the user by indicating which links were previously accessed. Clearing the Navigation History is not necessary to operate the CTC Interactive Web Application but can help the user particularly when entering a large number of patient records. Refer to your Internet browser's on-line help for further instruction or contact the NCI CTEP Help Desk.

The user can choose the **Tab** key or the mouse pointer to move from one set of data fields to the next or click directly in the data field to enter information. The **Enter** button must be pressed before leaving the **Adverse Event** data entry screen, otherwise the information will not be available for inclusion in a report. The information saved to the system is available to generate reports so long as the user remains in the system and provided the **Adverse Events** data entry screen is entered and saved. After exiting the system, the information can no longer be retrieved.

Unless otherwise noted, dates should be entered in the format MM/DD/YYYY, which means Month/Day/Year, where month and day must be two digits, and year must be four digits. For example, January 4, 1999 would be entered as 01/04/1999.

Several data fields have down arrow buttons next to them which when clicked provide access to a list of alternative values referred to as a **List of Values (LOV)**. Only the values available in the LOV can be selected to populate the field. Text entry is not available. LOVs available in the CTC Interactive Web Application are found only when creating reports or importing data.

System Requirements

The CTC Interactive Web Application runs on the MS Windows 95 operating system. To run the system, you need:

- An IBM[®]-compatible personal computer with an 80486sx, 80486, or higher processor (80486/20 or higher recommended),
- A hard disk with 10 megabytes (MB) of free space,
- Eight MB of random-access memory (RAM); 16 MB or more recommended,
- A Microsoft Mouse or other compatible pointing device,
- An EGA, VGA, or compatible display—VGA or higher recommended,
- Access to ORACLE[®] database via a user account, and
- Microsoft Windows 95.

The minimum browser requirements for proper functioning of this application are Internet Explorer version 4.0 or Netscape version 3.0 or later. These browsers are available for free download over the Internet.

Further Information

Please refer to the following resources for additional information.

- NCI CTEP Home Page: <http://ctep.info.nih.gov>
- NCI CTEP Common Toxicity Criteria , Version 2.0 (CTC, v2.0) document, publish date: April 30, 1999
- NCI CTEP Common Toxicity Criteria (CTC) Manual, anticipated publish date: Summer 1999
- NCI CTEP Common Toxicity Criteria, Version 2.0 (CTC, v2.0) - Notice of Modifications
- Common Toxicity Criteria Index Terms
- NCI CTEP Clinical Data Update System (CDUS) Instructions and Guidelines
- NCI Guidelines: Adverse Event Reporting Requirements for NCI Investigational Agents

To obtain further information, please contact the NCI CTEP Help Desk by telephone (301) 840-8202, fax (301) 948-2242, or E-mail at ncictephelp@ctep.nci.nih.gov.

Entering CTC Information

Search by Category

This section provides step-by-step instructions for entering information in the NCI CTC Interactive Web Application using the *Search by Category* option. You may enter information for as many records as required to include in your report. The scroll bars in each frame may be used to view more options.

1. Open the CTC Interactive Web Application and click the **CTC Version** number located in the left frame of the screen. The available search options appear in the right frame.

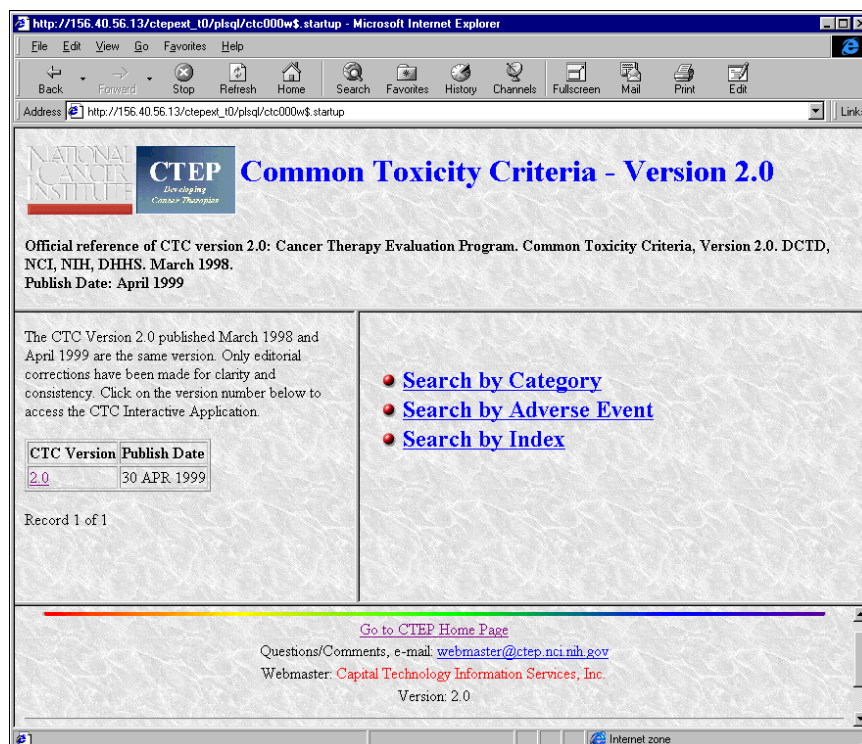


Figure 1. CTC Interactive Web Application Main Menu (search options displayed)

2. Click **Search by Category** in the right frame. The **Selection by Category** screen appears.

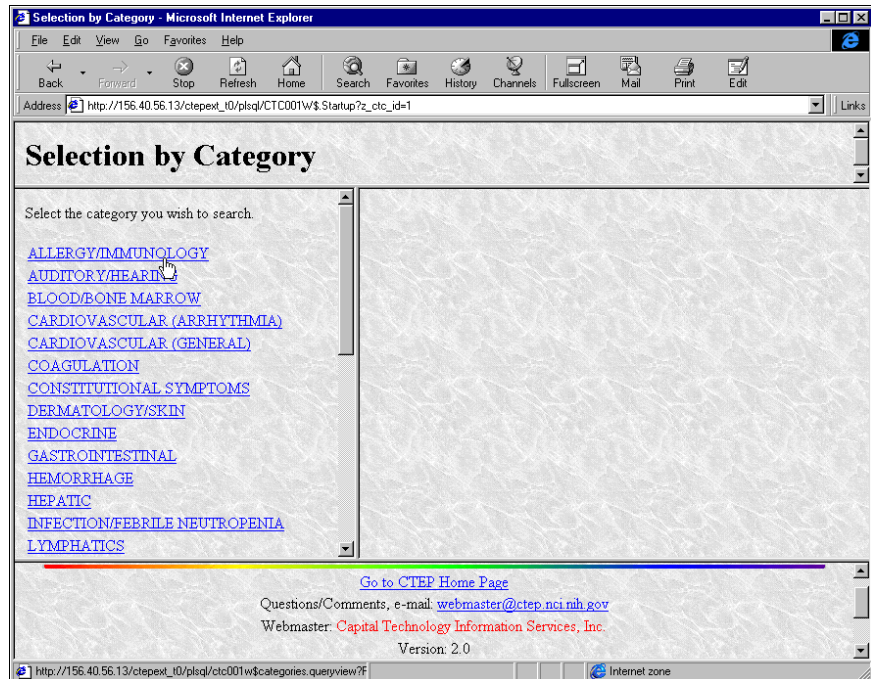


Figure 2. Selection by Category Screen

3. The **Selection by Category** screen lists 24 categories based on pathophysiology or anatomy. Category names appear in upper case letters. Click the adverse event category you wish to search. The adverse events associated with the chosen category are displayed in the right frame. Figure 3 illustrates the list of adverse events displayed when the ALLERGY/IMMUNOLOGY category is chosen. Terms appearing in the list preceded by (*) are *Navigation Terms* and are described on page 7.

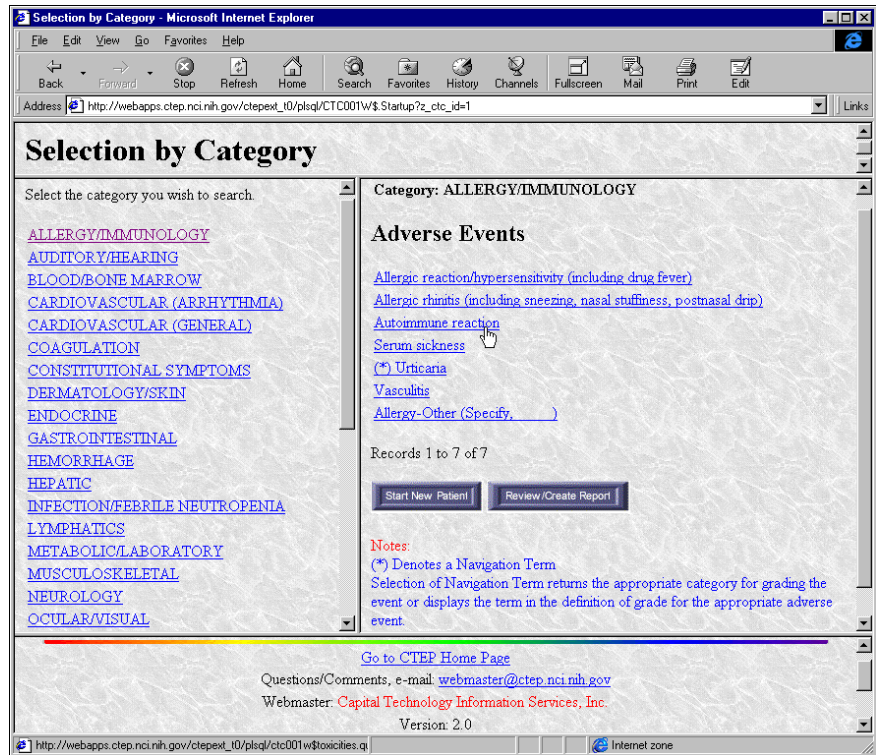


Figure 3. Selection by Category/Adverse Events Screen

4. Locate and click the adverse event you wish to review or report. The Adverse Events data entry screen appears.

Figure 4. Adverse Events Data Entry Screen

Steps to Enter Adverse Event Data

For each patient record, the following data are entered in the fields displayed on the **Adverse Events** data entry screen.

1. Click in the *selection circle* to the left of the **Grade** which best describes the adverse event you are reporting.
2. Click in the *selection circle* to the left of the **Attribution Code** which best describes the attribution of the adverse event you are reporting.
3. Enter the *patient identification number* in the **Patient Id:** field.
4. Enter the *protocol identification number* in the **Protocol Id:** field.
5. Enter the *course number* of the identified protocol in the **Course No.:** field.
6. Enter the *event date* in the **Date of Event: (MM/DD/YYYY)** field and click **Enter** to save the information.

You may search by another category, or review and create a report at this point by clicking the **Return to Category Selection** or **Review/Create Report** buttons located at the bottom of the **Adverse Events** data entry screen. The **Return to Main Menu** button is available in the bottom frame of the **Search by Category** screen if you wish to select another search option. Patient information (i.e., **Patient Id**, **Course No.**, and **Date of Event**) entered at this point will be carried over to the next record. This feature allows reuse of data elements when selecting multiple adverse events for a single patient. Data in any field can be changed by highlighting all or part of the field and entering new data. Alternatively, data from these fields can be eliminated for subsequent adverse event selections by clicking on the **Start New Patient** button.

Note: The definitions of the above data elements are described in the *CDUS Instructions and Guidelines* available on CTEP's Internet Home Page. It is suggested that the definitions be reviewed to better understand their use in the CTC Interactive Web Application.

Navigation Terms

A term preceded by (*) is a *Navigation Term*. Navigation Terms are intended to direct the user to the appropriate location in the CTC, v2.0 document where the term is included either as an adverse event or in the definition of grade(s) for an adverse event.

Terms included as an Adverse Event

Refer again to the *ALLERGY/IMMUNOLOGY* category (see Figure 3). For example, if “(*) Urticaria” were selected from the **Selection by Category/Adverse Events** screen, the *DERMATOLOGY/SKIN* category would be displayed (see Figure 5).

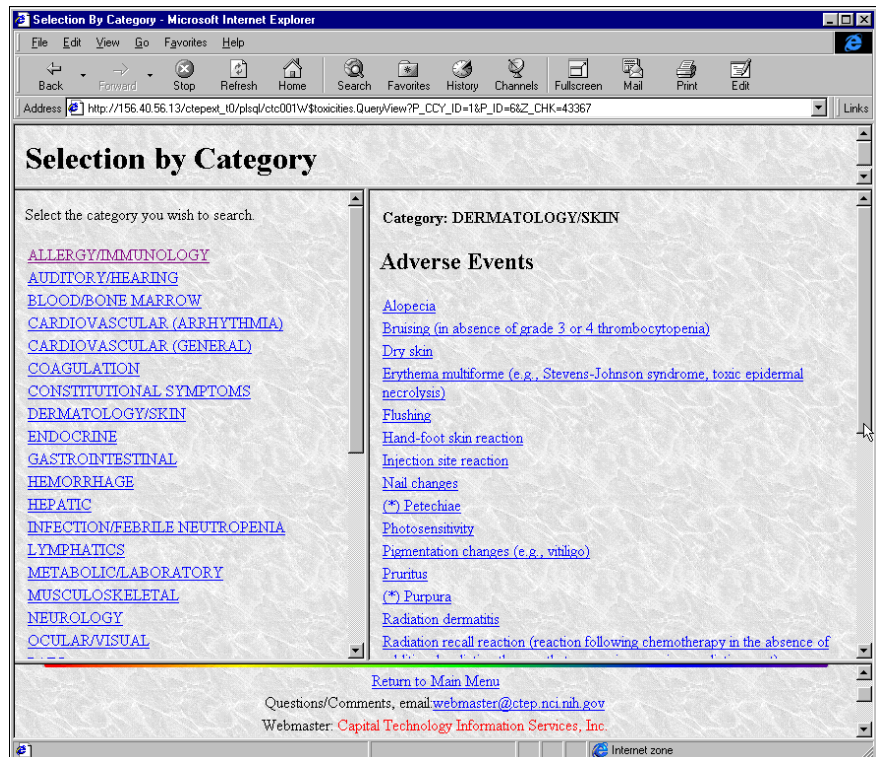


Figure 5. Selection by Category/Adverse Events Screen with the DERMATOLOGY/SKIN Category displayed.

To select “Urticaria”, use the scroll bar to move down the list of adverse events until “Urticaria” is visible.

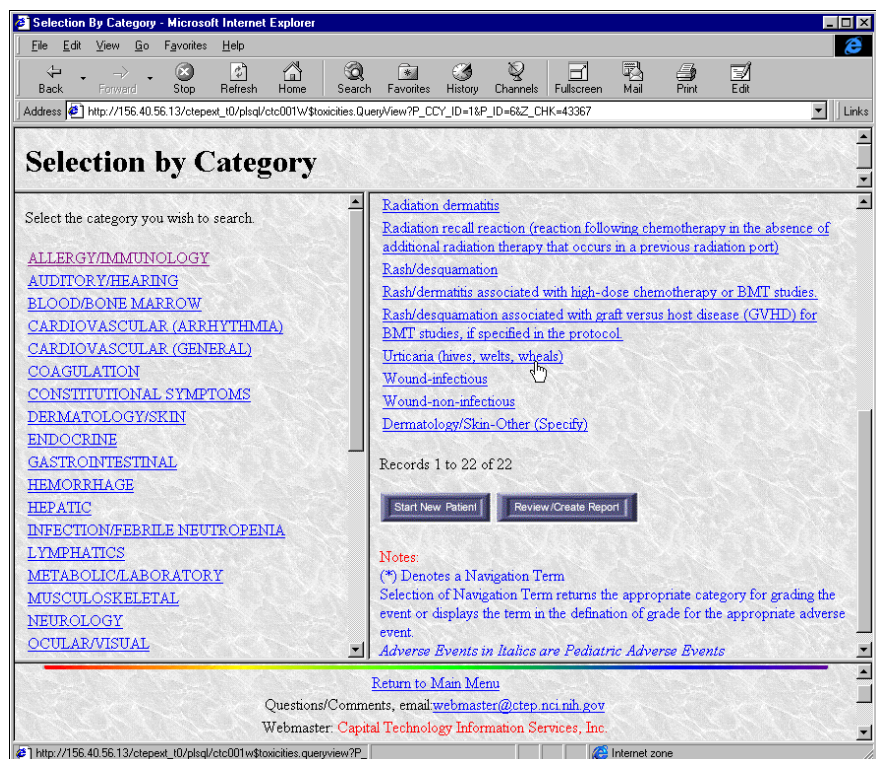


Figure 6. Selecting “Urticaria”

Upon selection of the adverse event, the **Adverse Events** data entry screen for “Urticaria” will appear. Refer to the *Steps to Enter Adverse Event Data* section of this guide (page 7) for detailed instructions on entering information in the **Adverse Events** data entry screen.

Terms included as an Adverse Event Grade Definition

In several instances, a Navigation Term is used to direct the user to a definition of an adverse event grade(s). For example, *Conductive hearing loss* is found under the Grade 3 definition of “Middle ear/hearing” from the AUDITORY/HEARING category. If the user selects “(*) Conductive hearing loss is graded as Middle ear/hearing,” the CTC Interactive Web Application redisplay the AUDITORY/HEARING category Adverse Events screen (see Figure 7).

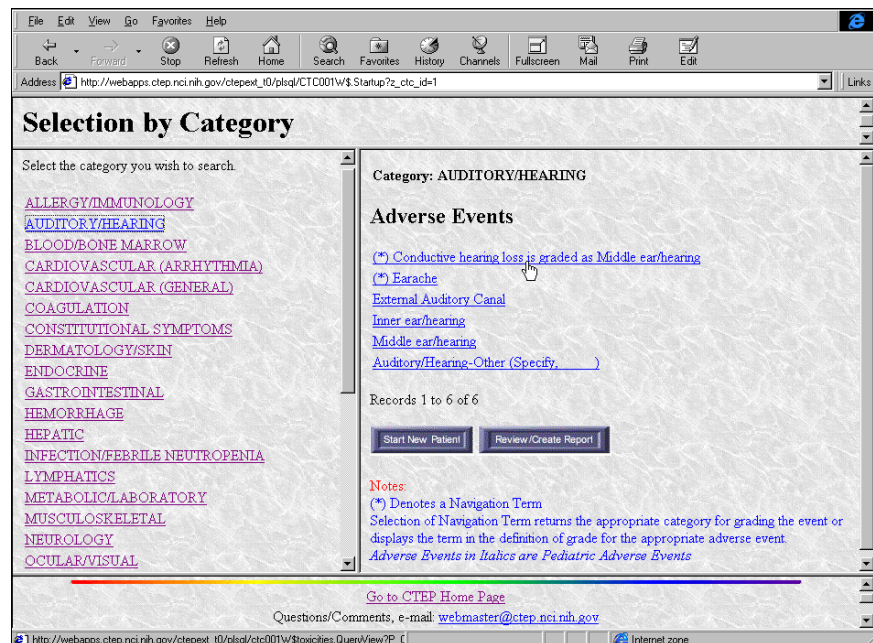


Figure 7. Selecting Conductive Hearing Loss from the AUDITORY/HEARING Category

The user must choose the “Middle ear/hearing” adverse event listed within the AUDITORY/HEARING category (see Figure 8).

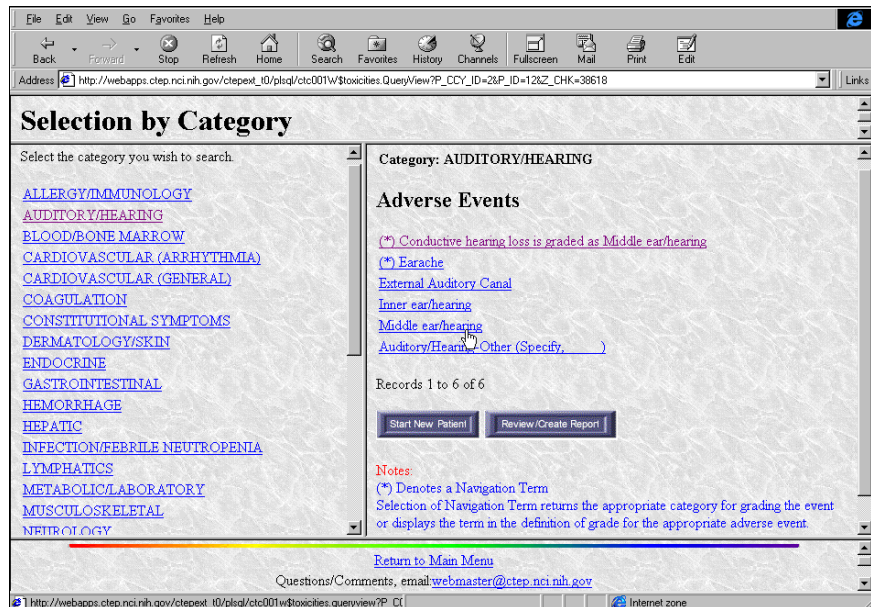


Figure 8. Selecting “Middle Ear/Hearing” from the AUDITORY/HEARING Category

Once selected, the “Middle ear/hearing” Adverse Events data entry screen is displayed (see Figure 9).

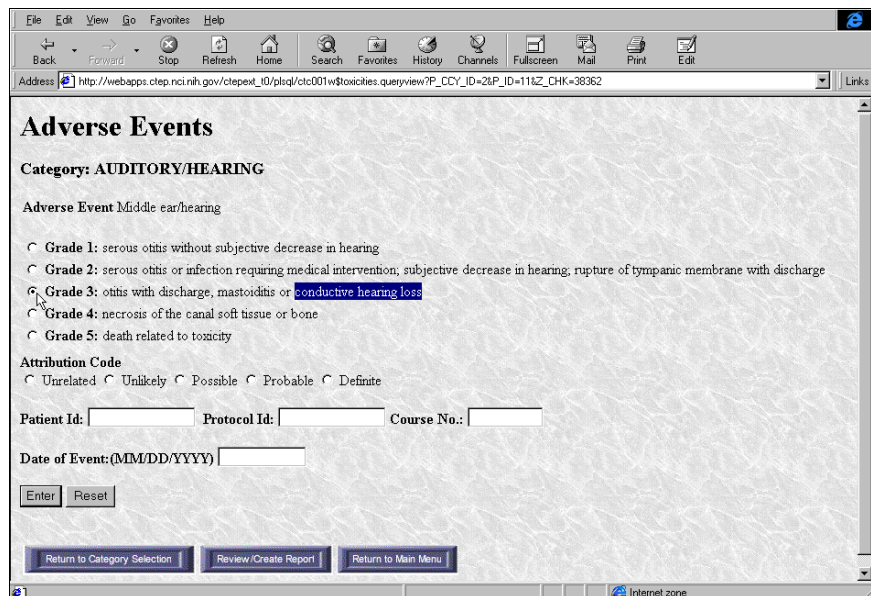


Figure 9. “Conductive Hearing Loss” highlighted on the “Middle Ear/Hearing” Adverse Event Data Entry Screen

“Conductive hearing loss” is located in the Grade 3 definition of the “Middle ear/hearing” adverse event. Refer to the *Steps to Enter Adverse Event Data* section of this guide (page 7) for detailed instructions on entering information in the **Adverse Events** data entry screen.

Also Consider

In some cases, an adverse event is associated with the occurrence of one or more additional events. These may or may not require grading, depending upon the specific case. In general, related adverse events must be graded when the related adverse event is clinically significant and provides relevant information to allow evaluators of the data to more fully characterize an adverse event. Within the CTC, v2.0 document, adverse events with possible related events include a note preceded by *Also consider*.

The CTC Interactive Web Application includes the *Also Consider* in the *Note*: area between the *Grade* and the *Attribution Code* options. In the following example, the adverse event “Hemorrhage/bleeding with grade 3 or 4 thrombocytopenia” was selected. The *Also consider* information appears after the sentence “This adverse event must be graded for any bleeding with grade 3 or 4 thrombocytopenia.”

Selection by Category : Toxicities - Microsoft Internet Explorer

File Edit View Go Favorites Help

Back Forward Stop Refresh Home Search Favorites History Channels Fullscreen Mail Print Edit

Address [http://156.40.56.13/ctepext_t0/plsql/ctc001w\\$toxicities.queryview?P_CCY_ID=11&P_ID=163&Z_CHK=63558](http://156.40.56.13/ctepext_t0/plsql/ctc001w$toxicities.queryview?P_CCY_ID=11&P_ID=163&Z_CHK=63558) Links

Adverse Events

Category: HEMORRHAGE

Adverse Event Hemorrhage/bleeding with grade 3 or 4 thrombocytopenia

☐ Grade 1: mild without transfusion

N/A Grade 2:

☐ Grade 3: requiring transfusion

☐ Grade 4: catastrophic bleeding, requiring major non-elective intervention

☐ Grade 5: death related to toxicity

Note: If the site is not listed, grade as Hemorrhage-Other (Specify site,). This adverse event must be graded for any bleeding with grade 3 or 4 thrombocytopenia. Also consider Platelets, Hemoglobin, Transfusion: platelets, Transfusion: pRBCs, site or type of bleeding.

Attribution Code

☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite

Patient Id: Protocol Id: Course No.:

Date of Event (MM/DD/YYYY)

Enter Reset

Return to Category Selection Review/Create Report Return to Main Menu

Figure 10. Also consider information highlighted on the Adverse Events Data Entry Screen

Once data entry is complete and **Enter** is clicked, the **Also Consider** screen automatically appears and displays all the adverse events that could possibly be related to the original adverse event (see Figure 11). The events are displayed in the left frame in alphabetical order.

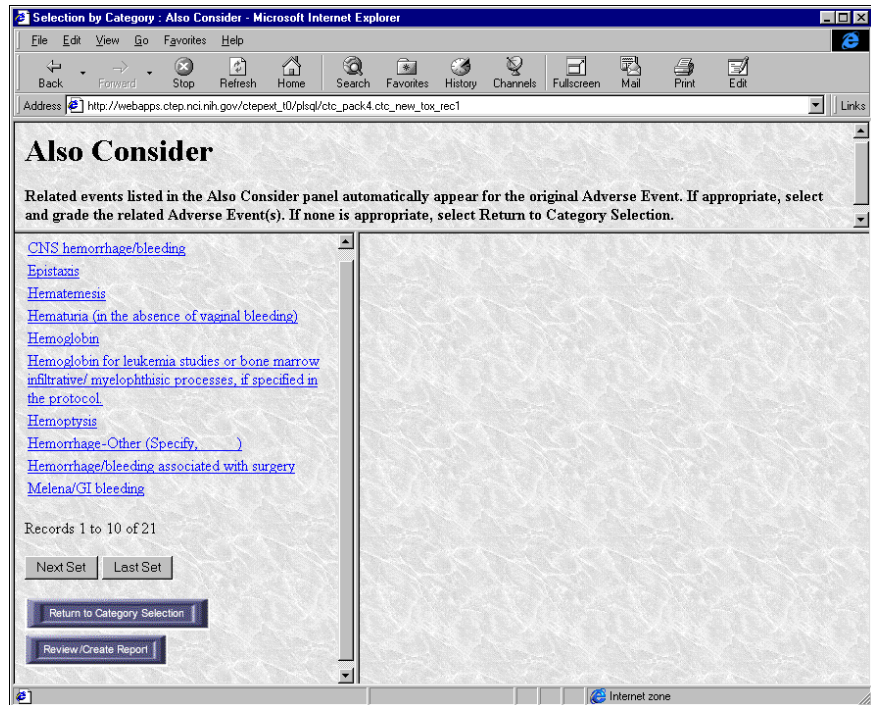


Figure 11. Also Consider Screen

The **First Set**, **Previous Set**, **Next Set** or **Last Set** buttons become available only when the list of adverse event exceeds the space on the screen. They are used to navigate through the list to locate a specific event.

Selecting one of the *Also consider* adverse events will display the **Also Consider/Original Adverse Event** data entry screen in the right frame (see Figure 12).

Figure 12. Also Consider/Original Adverse Event Data Entry Screen

Refer to the *Steps to Enter Adverse Event Data* section of this guide (page 7) for detailed instructions on entering information in the **Also Consider/Original Adverse Event** data entry screen.

Other (Specify _____)

The CTC, v2.0 document and the CTC Interactive Web Application include many common adverse events experienced by patients enrolled on cancer-related clinical trials. Any adverse event that cannot be located in the document or application can be graded under the *Other (Specify _____)* listing available within each adverse event category.

The current CTC Interactive Web Application does not accommodate text entry for *Other (Specify _____)*. The specific event can be added, however, to a saved spreadsheet or text file once a report is saved (see page 24 for additional details). Future versions of the CTC Interactive Web Application will allow text entry of the specific adverse event name under the *Other (Specify _____)* option.

To enter a patient record using this option, locate and click the *Other (Specify _____)* in the appropriate category using either of the three search options described in this guide. The **Adverse Event** data entry screen appears. Refer to the *Steps to Enter Adverse Event Data* section of this guide (page 7) for detailed instructions on entering information in the **Adverse Events** data entry screen.

Search by Adverse Event

This section provides step-by-step instructions for entering information in the NCI CTC Interactive Web Application using the *Search by Adverse Event* option. You may enter information for as many records as required to include in your report. The scroll bars in each frame may be used to view more options.

1. Open the CTC Interactive Web Application and click the **CTC Version** number located in the left frame of the screen. The available search options appear in the right frame (see Figure 1 on page 4).
2. Click **Search by Adverse Event** option in the right frame. The **Selection by Adverse Events** data entry screen appears.
3. Click the *alphabetic character* that corresponds with the initial letter of the adverse event you wish to search for. The **Adverse Events starting with letter:** column listing all adverse events beginning with the selected letter is displayed in the right frame.

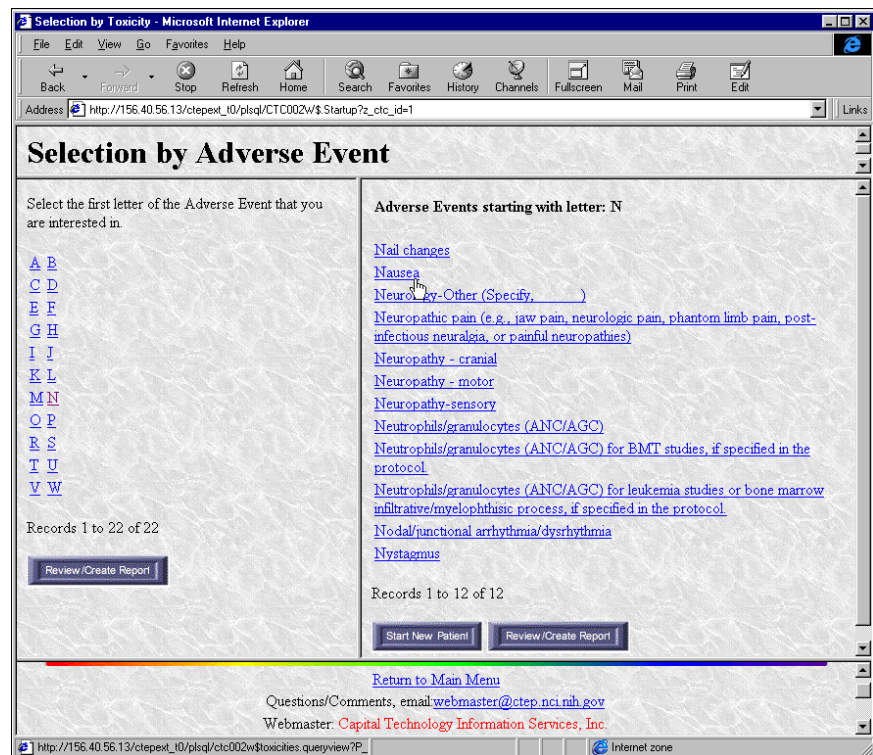


Figure 13. Selection by Adverse Events Data Entry Screen

4. Locate and click the adverse event you wish to review or report. The **Adverse Events** data entry screen appears.

Figure 14. Adverse Events Data Entry Screen

Refer to the *Steps to Enter Adverse Event Data* section of this guide (page 7) for detailed instructions on entering information in the **Adverse Events** data entry screen.

Search by Index

This section provides step-by-step instructions for entering information in the NCI CTC Interactive Web Application using the *Search by Index* option. The *Search by Index* option searches index term information from the *Common Toxicity Criteria Index Terms* document, and adverse event terms and definition of grade(s) from the *Common Toxicity Criteria, Version 2.0* document. Depending on the type of search used and the information entered as search criteria, the user can increase or decrease the number of potential matches the application returns.

The *Search by Index* provides two search types to assist the user in finding adverse events that are appropriate to the patient's situation. The *Minimal Search* limits the returns by restricting the search to information that exactly matches the search criteria. The *Extended Search* returns a greater number of adverse event possibilities by automatically broadening the search criteria. The sections below provide examples to help illustrate the differences between the two search methods.

Search Type 1: The Minimal Search

The *Minimal Search* examines index terms, adverse event names, and the adverse event grade definitions and returns adverse events based on an exact match of the criteria entered in the **Index Term** field. The *Minimal Search* provides a narrower return of adverse events from which to select and should be used before conducting an *Extensive Search*.

For example, if “ast” is entered in the **Index Term** field, the adverse event “SGOT (AST) (serum glutamic oxaloacetic transaminase)” is displayed (see Figure 15).

Adverse Event	Category
SGOT (AST) (serum glutamic oxaloacetic transaminase)	HEPATIC
Records 1 to 1 of 1	

Figure 15. Minimal Search on “ast”

Search Type 2: The Extensive Search

The *Extensive Search* returns adverse events from the same search areas (i.e., index terms, adverse events, and grade definitions) as described above, but automatically broadens the search criteria to display a wider return of adverse events from which to select. The *Extensive Search* displays adverse events based on exact matches and/or partial matches to the search criteria. The *Extensive Search* also ignores all typographic symbols such as hyphens (-) or virgules (/) to provide a greater number of possible returns.

Depending on the criteria used, the *Extensive Search* may possibly provide too many selections from which to choose. It is recommended that the *Minimal Search* always be conducted before conducting an *Extensive Search*.

Using the same search criteria, “ast,” the Extensive Search displays significantly more returns than originally displayed in Figure 15 (see Figures 16 and 17).

Adverse Event	Category
External Auditory Canal	AUDITORY/HEARING
Middle ear/hearing	AUDITORY/HEARING
Hemolysis (e.g., immune hemolytic anemia, drug related hemolysis, other)	BLOOD/BONE MARROW
Hypertension	CARDIOVASCULAR (GENERAL)
Partial thromboplastin time (PTT)	COAGULATION
Fatigue (lethargy, malaise, asthenia)	CONSTITUTIONAL SYMPTOMS
Gynecomastia	ENDOCRINE
Gastric ulcer (requires radiographic or endoscopic documentation)	GASTROINTESTINAL
Gastritis	GASTROINTESTINAL
Gastrointestinal-Other (Specify, _____)	GASTROINTESTINAL
Salivary gland changes	GASTROINTESTINAL
Taste disturbance (dysgeusia)	GASTROINTESTINAL
Epistaxis	HEMORRHAGE
Hematemesis	HEMORRHAGE
Hemoptysis	HEMORRHAGE
Hemorrhage-Other (Specify, _____)	HEMORRHAGE
Hemorrhage/bleeding associated with surgery	HEMORRHAGE
Hemorrhage/bleeding with grade 3 or 4 thrombocytopenia	HEMORRHAGE
Hemorrhage/bleeding without grade 3 or 4 thrombocytopenia	HEMORRHAGE
Melena/GI bleeding	HEMORRHAGE
Records 1 to 20 of 29	

Figure 16. Extensive Search on “ast,” records 1 to 20 of 29

Adverse Event	Category
Rectal bleeding/hematochezia	HEMORRHAGE
Vaginal bleeding	HEMORRHAGE
Liver dysfunction/failure (clinical)	HEPATIC
SGOT (AST) (serum glutamic oxaloacetic transaminase)	HEPATIC
Dyspnea (shortness of breath)	PULMONARY
Voice changes/stridor/larynx (e.g., hoarseness, loss of voice, laryngitis)	PULMONARY
Operative injury to bladder and/or ureter	RENAL/GENITOURINARY
Urinary electrolyte wasting (e.g., Fanconi's syndrome, renal tubular acidosis)	RENAL/GENITOURINARY
Secondary Malignancy-Other (Specify, _____) excludes metastasis from initial primary	SECONDARY MALIGNANCY

Records 21 to 29 of 29

Figure 17. Extensive Search on “ast,” records 21 to 29 of 29

The additional events displayed are due primarily to the partial match on the adverse event name or the grade definition. For example, the adverse events “Partial thromboplastin time (PTT),” “Fatigue (lethargy, malaise, **asthenia**),” and “Gynecomastia” all include “ast” within their spelling as highlighted in bold type. The Grade 3 definition for “External Auditory Canal” includes the word “**mastoiditis**” which is also spelled with “ast.”

Adverse Events: External Auditory Canal

☐ **Grade 1:** external otitis with erythema or dry desquamation
☐ **Grade 2:** external otitis with moist desquamation
☐ **Grade 3:** external otitis with discharge, **mastoiditis**
☐ **Grade 4:** necrosis of the canal soft tissue or bone
☐ **Grade 5:** death related to toxicity

Note: Changes associated with radiation to external ear (pinnae) are graded under Radiation dermatitis in the DERMATOLOGY/SKIN category.

Attribution Code
☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite

Patient Id: **Protocol Id:** **Course No.:**

Date of Event: (MM/DD/YYYY)

Figure 18. Extensive Search on “ast,” “External Auditory Canal” grade definition

Conducting an Index Search

1. Open the CTC Interactive Web Application and click the **CTC Version** number located in the left frame of the screen. The available search options appear in the right frame (see Figure 1 on page 4).
2. Click **Search by Index** in the right frame. The **Selection by Index/Adverse Events** screen appears.

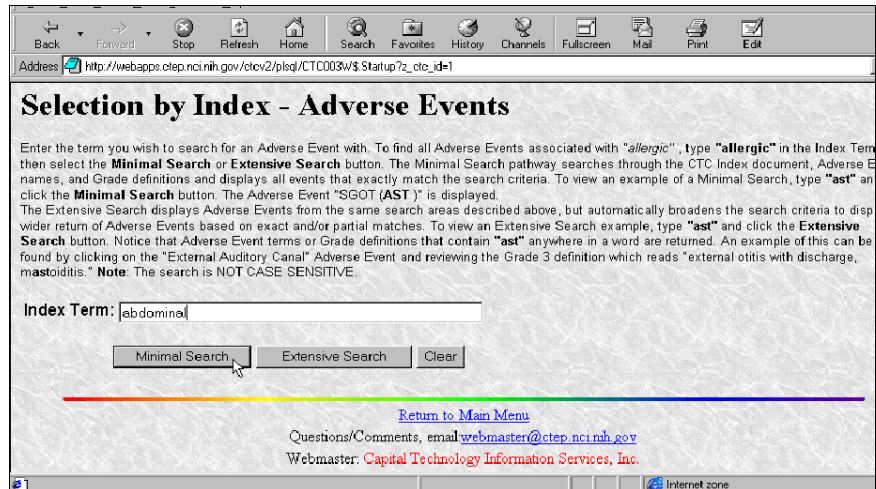


Figure19. Searching “abdominal” in the Selection by Index/Adverse Events Screen

3. Click within the **Index Term** field and enter the word you wish to search for. Upper or lowercase characters can be entered in the **Index Term** field with the same return results.
4. Click either the **Minimal Search** or **Extensive Search** button. The **Clear** button can be clicked to delete the existing search criteria to allow entry of new criteria. The adverse events matching the search criteria are displayed in the left frame of the **Adverse Event** screen.

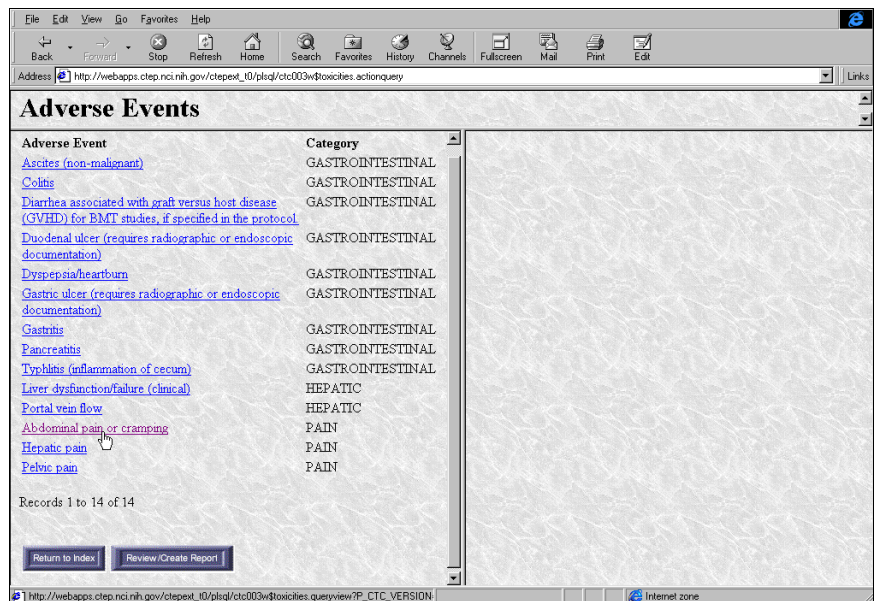


Figure 20. Adverse Event Screen

5. Click the **Adverse Event** you wish to enter data for in the left frame. The specified **Adverse Events** data entry screen is displayed in the right frame.

Figure 21. Adverse Events Data Entry Screen

Refer to the *Steps to Enter Adverse Event Data* section of this guide (page 7) for detailed instructions on entering information in the **Adverse Events** data entry screen.

Reviewing and Using CTC Information

Creating Reports

If you wish to review the entries you have made during a session, or when you are ready to save an electronic copy of the entries you have made, select the **Review/Create Report** button from any screen where the option is available. A second Internet browser session appears that displays the **Graded Records** screen showing all entries that have been made during the session.

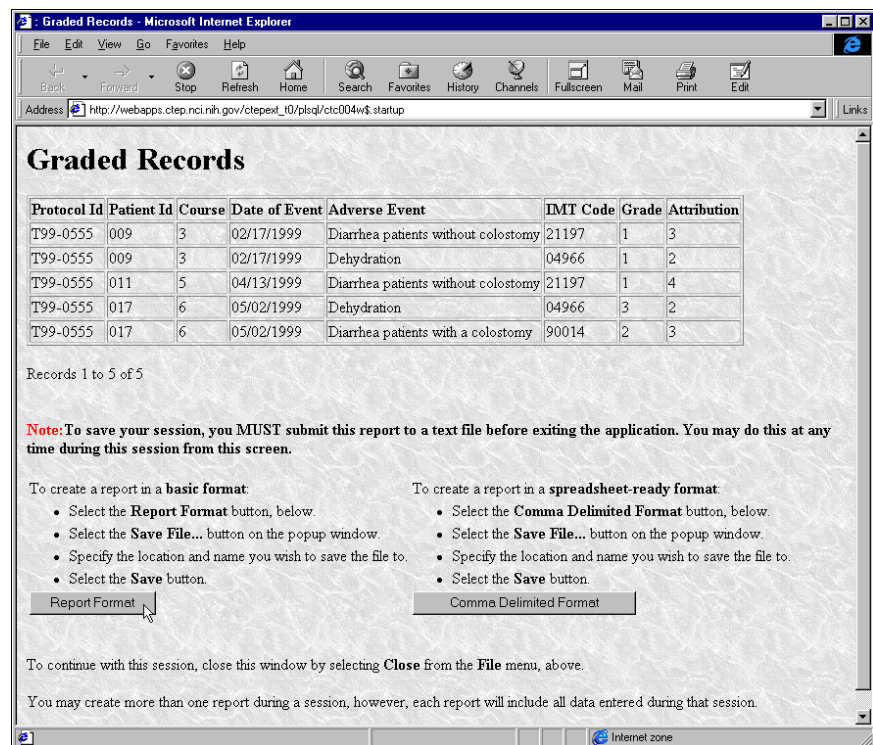


Figure 22. Graded Records Screen

Creating Reports in Microsoft Excel

Once you have generated the report in the **Graded Records** screen, you may wish to import the data into a Microsoft Excel spreadsheet and store it for later reference. Microsoft Excel spreadsheet files provide the ability to sort, arrange the data specific to your reporting needs, and combine data generated from multiple reports.

The **Copy/Paste** command and the **Import Text Wizard** are the methods explained in the following sections to import report data into a Microsoft Excel spreadsheet.

Pasting Data into a Microsoft Excel Spreadsheet

Follow the instructions below to copy and paste the report data directly from the **Graded Records** screen.

1. Complete all patient record entries and select the **Review/Create Report** button from any screen where the option is available. The **Graded Records** screen appears showing all entries made during the session.
2. Select the report data by placing the mouse pointer over the top, left corner of the report. When the mouse pointer converts to an I-bar, press and continuously hold down the left mouse button while dragging the I-bar across the report data.

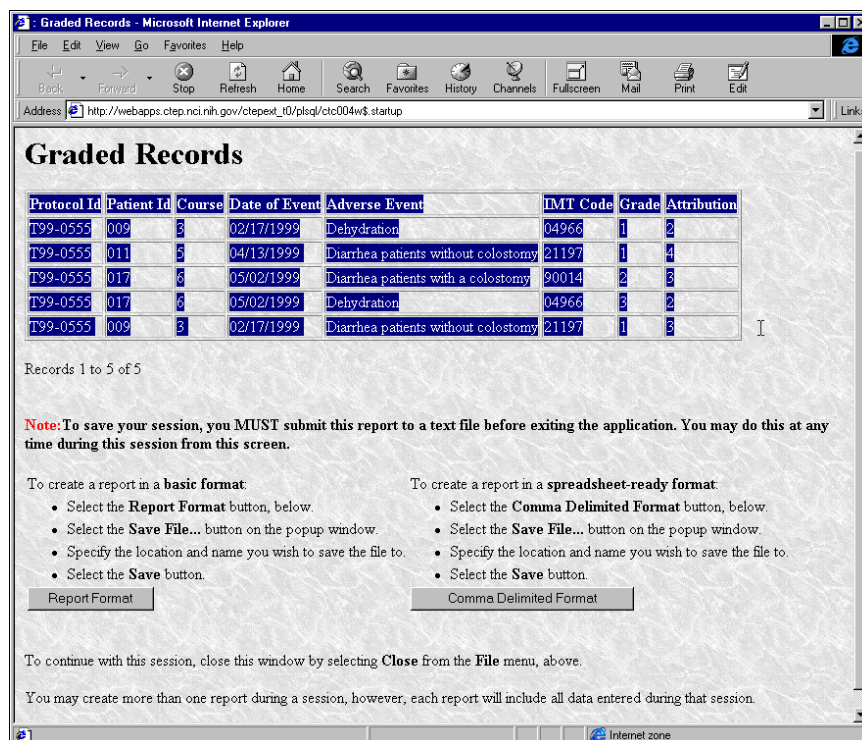


Figure 23. Selecting Report Data from the Graded Records Screen

3. From the Menu bar, click **Edit** and select **Copy** or press **Control + C**. The data is copied to the computer's internal clipboard.
4. Open the Microsoft Excel application and open a new spreadsheet file.
5. Click in the top, left cell of the spreadsheet. Click **Edit** from the Menu bar and select **Paste** or press **Control + V**. The data is copied into the Excel spreadsheet. You may need to adjust the column sizes to improve readability.

	A	B	C	D	E	F	G	H	I
	Protocol Id	Patient Id	Course	Date of Event	Adverse Event	IMT Code	Grade	Attribution	
1									
2	T99-0555	9	3	2/17/99	Dehydration	4966	1	2	
3	T99-0555	9	3	2/17/99	Diarrhea patients without colostomy	21197	1	3	
4	T99-0555	11	5	4/13/99	Diarrhea patients without colostomy	21197	1	4	
5	T99-0555	17	6	5/2/99	Dehydration	4966	3	2	
6	T99-0555	17	6	5/2/99	Diarrhea patients with a colostomy	90014	2	3	
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									

Figure 24. Pasting Report Data to the Spreadsheet

6. Use any of Excel's features to arrange and/or sort the data to meet your reporting needs. Use the **Save As** command from the **File** option on the Menu bar to save the new Excel spreadsheet file.

Importing Comma Delimited Text into a Microsoft Excel Spreadsheet

From the **Graded Records** screen (see Figure 27), a report can be saved electronically in one of two formats: *Report Format* or *Comma Delimited Format*. The *Report Format* will produce an easily readable, formatted document. The *Comma Delimited Format* should be used if you plan to import this data into a spreadsheet or database.

The **Graded Records** screen provides step-by-step instructions on how to save the file to a directory on your computer; these instructions are also detailed below.

1. Press either the **Report Format** or **Comma Delimited Format** button. The **File Download** dialog box appears.

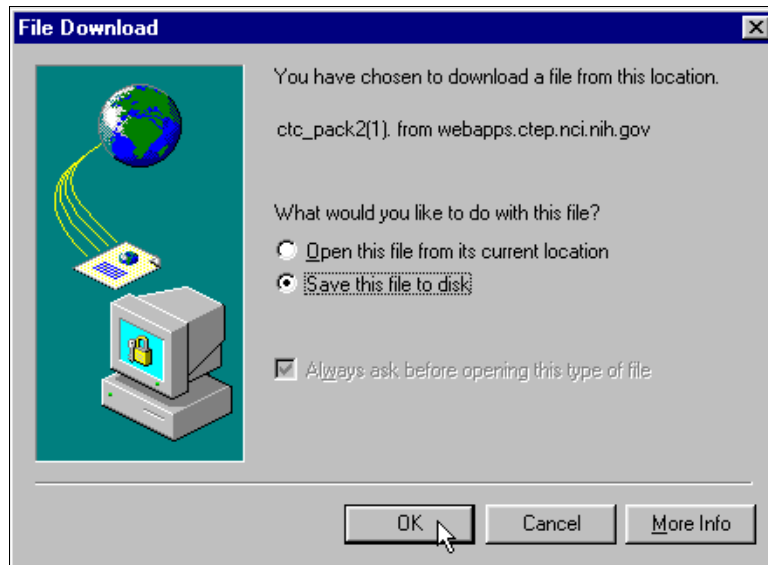


Figure 25. File Download Dialog Box

2. To save the file using either format option, click the **Save this file to disk** radio button and click **OK**. The **Save As** dialog box appears.

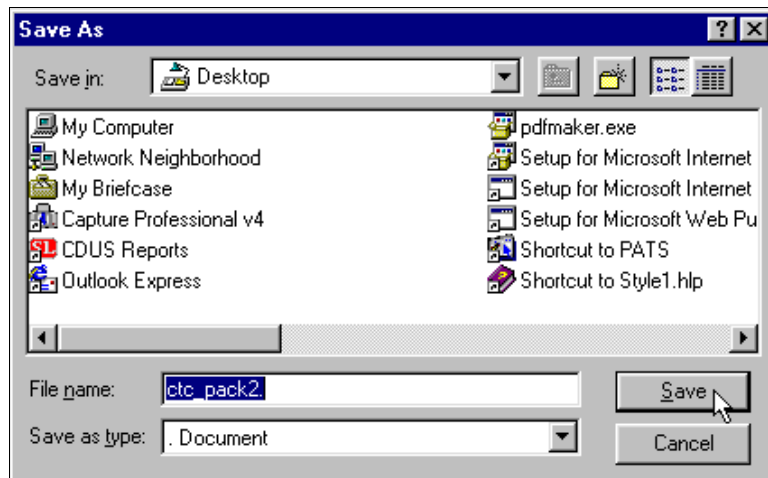


Figure 26. Save As Dialog Box

3. In the **Save in:** field, note the directory in which you saved your file to easily locate it later or specify a new location on your computer. In the **Save as type:** field, verify that the file type is *Document*. In the **File name:** field, note the system-generated file name or specify a new name for the file, and follow that name with the extension *.txt*. Click **Save**. The system will provide a **Download Complete** message. Click **OK**.

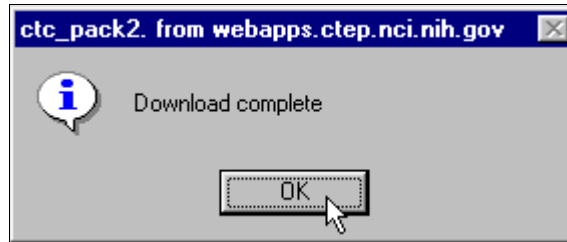


Figure 27. Download Complete Message

Once the file is saved, it can be opened using any standard word processing application such as Microsoft WordPad, Microsoft Word, WordPerfect, etc. If saved in comma delimited format, it can be imported into a spreadsheet application (e.g., Microsoft Excel or Lotus), or with minimal programming effort, into a database application. Continue the step-by-step instructions below to import the saved, comma delimited file into an Excel format using the **Import Text Wizard**.

The CTC Interactive Web Application can now be closed or used to continue entering additional information. Once the application is closed, the information you entered is eliminated from the system.

4. Open the **Microsoft Excel** application.
5. Click **Open** from the **File** menu to locate your saved comma delimited report file. The **Open** dialog box appears.

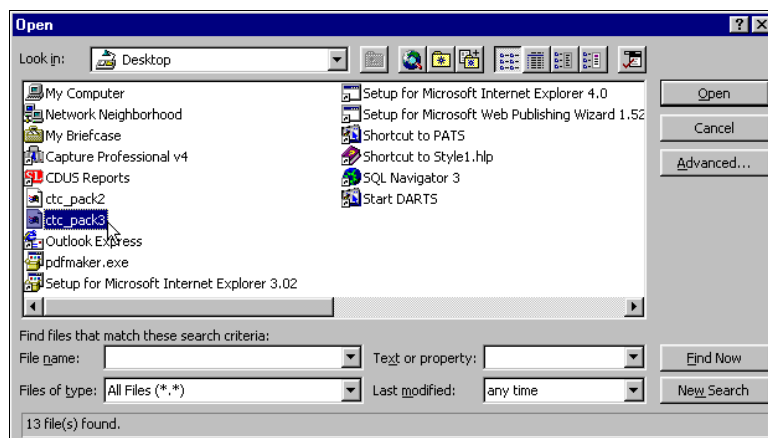


Figure 28. Open Dialog Box

6. Use the down arrow in the **Look in:** field and/or the **Up One Level** button to locate the drive on which you saved the file, and select the appropriate directory.
7. Ensure that **All Files (*.*)** is selected in the **Files of type:** field.
8. Double-click the saved file to begin the import. The first **Text Import Wizard** dialog box appears.

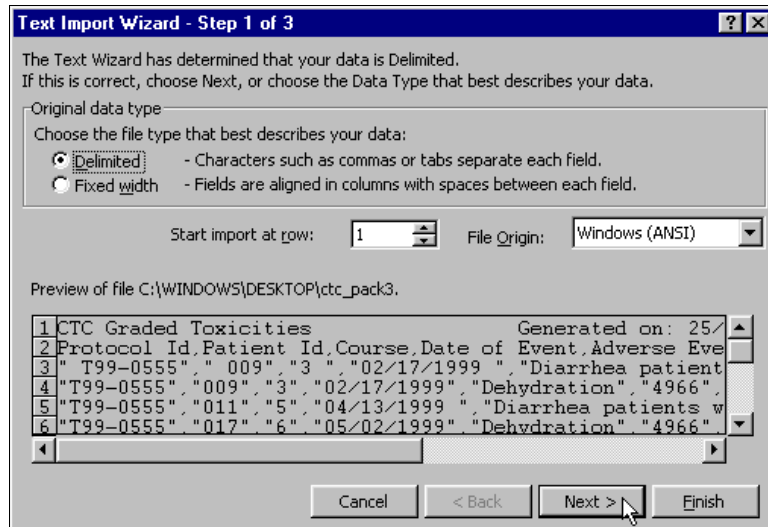


Figure 29. Text Import Wizard-Step 1 Dialog Box

9. Ensure that **Delimited** is selected as the file type in the **Original Data Type** area and click **Next**. The second **Text Import Wizard** dialog box appears.

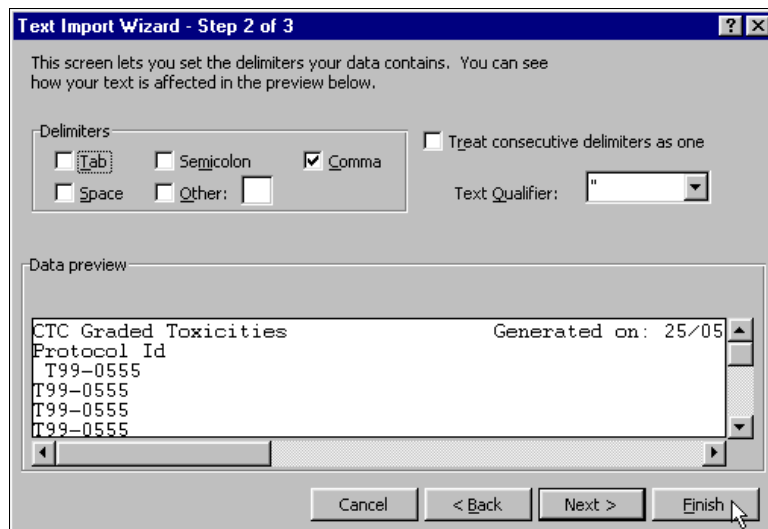


Figure 30. Text Import Wizard-Step 2 Dialog Box

10. Click the **Tab** option to deselect the tab format, click **Comma** in the **Delimiters** area, and click **Finish**. The file is imported into the **Microsoft Excel** file. You may need to adjust the column sizes to improve readability.

Microsoft Excel - ctc_pack2

File Edit View Insert Format Tools Data Window Help

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1	CTC Graded Toxicities							
2	Protocol Id	Patient Id	Course	Date of Event	Adverse Event	CTEP Code	Grade	Attribution
3	T99-0555	9	3	2/17/99	Diarrhea patients without colostomy	21197	1	3
4	T99-0555	9	3	2/17/99	Dehydration	4966	1	2
5	T99-0555	11	5	4/13/99	Diarrhea patients without colostomy	21197	1	4
6	T99-0555	17	6	5/2/99	Dehydration	4966	3	2
7	T99-0555	17	6	5/2/99	Diarrhea patients with a colostomy	900146	2	3
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Ready

Figure 31. Microsoft Excel File

11. Use any of Excel's features to arrange and/or sort the data to meet your reporting needs. Use the **Save As** command from the **File** option on the Menu bar to save the new Excel spreadsheet file.